UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Offic
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

CV

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/194,165	05/11/99	PERKES L	09143/005001

HM22/0622

RICHARD J ANDERSON
FISH & RICHARDSON
60 SOUTH SIXTH STREET
SUITE 3300
MINNEAPOLIS MN 55402

EXAMINER	
PATTEN, P	
ART UNIT	PAPER NUMBER
1651	13

DATE MAILED: 06/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/194,165	Applicant(s) Perkes, L.
	Examiner Patricia Patten	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 10, 2001*.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above, claim(s) *32-47* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-31* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 12

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Claims 1-47 are pending in the application.

Claims 32-37 were withdrawn from further consideration on the merits in Paper No. 9.

Claims 1-31 and 38-47 were presented for examination on the merits.

Election/Restriction

Newly submitted claims 38-47 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 38-47 are drawn to a composition comprising at least two flavanoids and at least one enzyme. These claims are properly restrictable under U.S. Restriction practice in that the claims lack a 'Special Technical Feature' with regard to 371 rules because the composition of claim 1 was known in the art at the time the Instant invention was made. Restriction is proper because the newly submitted claims require two flavanoids as opposed to only one flavanoid. Dependant upon the flavanoid, a combination of two flavanoids could have an additive or synergistic effect which would render the product patentably distinct from the products of Claims 1-31.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the

merits. Accordingly, claims 38-47 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-31 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons set forth in the Office Action dated 10/27/2000.

Applicants arguments filed 5/10/01 were considered, but not found persuasive.

Applicant's argue that "...any dietary supplement that contains an enzyme and an extract containing a flavonoid while being ineffective for inhibiting platelet activity and LDL cholesterol oxidation in a mammal at a dosage of about 30 mg/Kg or less is not within the scope of the claims." However, Applicants have not demonstrated that all flavanoids will inhibit platelet activity and LDL cholesterol. It was known at the time of the instant invention, as discussed in the Office Action dated 10/27/00 that quercetin decreased platelet aggregation as evidenced by

Pace-Asciak et al. (1995). However, Applicant's are asserting that if a supplement containing a flavanoid and an enzyme does not have platelet inhibiting activity, then said supplement is not within the scope of the present claims. However, Applicants have not shown where any specific flavanoid is responsible for the platelet lowering effect. Rather, one of skill in the art, relying on the prior art, would assume that because the ingredients in PROVEX contain quercitin, therefore it appears that it was the quercitin which had the platelet lowering effect. Applicants state in the Specification "The present invention involves the discovery that the combination of certain flavonoids and enzymes in the form of.....reduces the dosage of supplement needed to effectively reduce platelet activity and LDL cholesterol oxidation in a mammal" (p.2, lines 26-30). However, it is not known exactly what flavanoids Applicants are referring to. There are numerous flavanoids known in the art. All of these flavanoids have not shown beneficial effects toward platelet reducing activity:

Breadth alone is not the issue, however. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

> "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, **he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope**

of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

It appears that Applicant's have displayed positive results with regard to PROVEX and platelet inhibition. However, it is unclear with regard to exactly what PROVEX is because it is not known what proceedure is needed in order to produce such a composition.

Applicant's further argue that the Instant specification teaches that "...extracts containing a flavonoid can be obtained from grape seeds, grape skins, ginko biloba, bilberry, and other similar fruits" and in light of this teaching, the ordinary artisan would have been capable of using standard extraction procedures to obtain an extract which contained a flavanoid. While this is generally believable because it was known that quercetin, a flavonol obtained from fruit, had platelet inhibitory activity, it is not known what other flavanols would work commensurate in scope with the claimed invention without an adequate teaching of such. Applicant's argument with regard to 'standard extraction procedures' is not clearly understood. What exactly is a 'standard extraction procedure'? There are a myriad of extraction protocols which one of skill in the art could potentially perform on any

of the fruits listed in the Instant specification. However, in order to obtain similar results to the ones displayed via use of PROVEX, one would necessarily need critical information regarding exact extraction procedures because respective extraction protocols will necessarily yield different products which would result in different clinical effects.

The Instant specification lacks guidance with regard to any extraction protocols. Thus, the 'extract' from all of the fruits listed in the Specification could simply be quercitin, because quercitin is found in a wide variety of fruits as indicated by Balch et al. (1997). However, it is not clear exactly what is contained in the extracts. In such a situation, it is suggested that the product be claimed by a product-by-process type claim in order to more fully define the composition. However, in the instant case it is unclear, due to lack of description in the Instant specification, what procedure is performed in order to achieve the present composition.

Claim Rejections - 35 USC § 102

Claims 1-5, 9-11 and 22 remain rejected under 35 U.S.C. 102(b) as being anticipated by Balch et al. (1997).

Applicant's arguments filed 5/10/01 were considered, but not found persuasive.

Applicant argues that Balch et al. did not specifically disclose a composition which contained an enzyme and a flavanoid. Applicant is referred to Balch et al. p. 21, col. 1,

where they clearly teach that "Activated Quercetin from Source Naturals is a good source of quercetin. It also contains two other ingredients that increase its efficacy: bromelan, an enzyme from pineapple, and vitamin C....". Thus, Balch et al., clearly anticipated the claimed invention.

Claim Rejections - 35 USC § 103

Claims 1-24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gaynor et al. (US 5,904,924) in view of Balch et al. (1997) and further in view of Handel et al. (US 5, 387,422).

Please note that in the Office Action dated 10/27/00 Claims 14-20 were inadvertently left out from the rejection, however, it was clear from the description of the claims under the 35 U.S.C. 103(a) heading (or where the supplement contains grape seed extract, grape skin extract, ginko biloba extract, bilberry extract, quercetin, fungal protease, acid stable protease and bromelain.....) that these claims were rejected on the merits, however, the particular claim numbers were inadvertently omitted.

Applicant's arguments filed 5/10/01 were considered, but were not persuasive.

Applicant is reminded that the term 'effective for reducing platelet activity' is merely an intended use for the composition of the claim, and holds little patentable weight. Further: A rejection under 35 U.S.C. § 103 based upon the combination of references is not deficient

solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention. Ex parte Raychem Corp, 17 U.S.P.Q. 2d 1417.

In the present case, it would have been obvious to have combined the composition disclosed by Gaynor et al. with bromelain because quercetin was intrinsic to their composition, and because quercetin was advantageously combined with bromelain in order to enhance digestion of the flavanoid as disclosed by Balch et al.

Where claims state '...in the form of' is merely an extrinsic charachteristic, which would not have materially changed the composition.

Claims 25-31 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Pace-Asciak et al. (1995) in view of Balch et al. (1997).

Applicant's arguments are centered around the conclusion that Balch et al. did not disclose a flavanoid in combination with an enzyme. It was indicated *supra* that Balch et al. clearly disclosed such a composition, and thus, the rejection stands: it would have been obvious to have inhibited platelet activity in a mammal by use of a flavanoid and an enzyme as deemed in the Office Action dated 10/27/00.

No Claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Jon P. Weber, Ph.D.
Primary Examiner